REMARKS

Introduction

Status of claims

Claims 1 through 11 are pending in this application. Claims 1-11 are rejected.

Claims 1, 2, 5, 6 and 11 have been amended. Claim 4 has been cancelled, and new claims 12-19 which are based on the subject matter deleted from claims 2, 4, 5 and 6, are added. Accordingly, no new matter has been added.

The Office Action

Claims 1 through 11 have been examined on the merits.

Rejection under 35 U.S.C. § 112

Claims 2, 4, 5, 6 and 11 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4, 5 and 6 are indefinite because of improper use of Markush language. Applicant has amended Claims 2, 5 and 6 as suggested by the Examiner; Claim 4 has been deleted.

Claims 2, 4, 5 and 6 have further been rejected for their contents of preferred subject matter in parenthesis and after terms like "such as" respectively. Applicant has deleted all such language in parenthesis or indicated as being preferred from these Claims and has made those preferred

embodiments the subject matter of newly added Claims 12 through 19.

It is deemed that due to this amendment, this rejection under 35 U.S.C. § 112 is now moot.

Claim 11 has been rejected under 35 U.S.C. § 112, for being indefinite because of lacking an antecedent basis for "then freeing it from solvents or dispersion media". Applicant has amended Claim 11 to include an antecedent basis for "then freeing it from solvents or dispersion media".

Accordingly, also this rejection under 35 U.S.C. § 112 is deemed to be moot.

Finally Claim 11 has been rejected under 35 U.S.C. § 112 as being dependant on Claim 1. It is presumed that the process of Claim 11 will not make a product according to Claim 1 (an encapsulated product) because Claim 11 requires that the active substance is mixed with the shell-forming substance and thus does not produce a capsule in which an active material is surrounded by a shell-forming substance.

This rejection is respectfully traversed, and it is assured that indeed the process according to Claim 11 does yield in an encapsulated product as claimed in Claim 1. This is because of the nature of the employed materials. For clarification purposes Claim 11 has been amended to include the shell-forming material as defined in Claim 1. The specification at page 10 sets forth that the core material forms a stable complex with the shell-forming material, and thus the shell-forming material gathers around the core material and surrounds it from all sides. Thus, already in the mixture the spheres (capsules) are formed. Upon removal of the solvent or dispersion media, e.g. by spray-drying the capsules of Claim 1 are obtained. For illustration purposes Applicants attach a picture to this response (Appendix A). This picture - provided by co-inventor B. Kunz - shows encapsulated *L. reuteri* micro organisms according to the

It is thus believed that this rejection under 35 U.S.C. § 112 is now moot.

Rejection under 35 U.S.C. § 102

Claims 1, 2, 4 and 6 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Ghani (US 6,120,811). It is held that Ghani discloses a core material of corn cob which is coated with a biologically active substance, an enzyme, and encapsulated by a shell forming material as in Applicants' Claim 1. The dietary fiber is cellulose.

This rejection is traversed for the reasons set forth below.

The main and most important difference between the Ghani microgranules and the present microcapsules resides in the particle form itself. While the "granules" according to Ghani are irregularly shaped particles or agglomerated particles exhibiting broken edges revealing the interior of the particles, the capsules according to the present invention have a core which is surrounded on all sides by a shell (see capsule in Appendix A, attached hereto). Ghani prepares its granules in a fluidized bed granulator (see Ghani at col. 3, ln. 65-67).A fluidized bed implies that the particles are held in a "hovering" state by a constant flow of air. The particles permanently collide with one another, resulting in a permanent abrasion process. Therefore, even if capsules were initially formed in the Ghani process at least the outer shell would be perforated through the abrasion process if not partially destroyed. In any case, the resulting granules are no capsules within the meaning of present Claim 1.

In view of the foregoing, it is respectfully submitted that the instant rejection under 35 USC §102(a) should be withdrawn.

Rejection under 35 U.S.C. § 103(a)

biologically active substance which is protected in the rumen while efficiently released in the abomasum and following digestive tract. It is the Examiner's position that the biologically active substance is a vitamin, mineral or antibiotic, the fiber is considered to be the crystalline

cellulose and that it is obvious that chitosan can be the shell-forming material.

This rejection is respectfully traversed for the following reasons.

According to Ueda et al. the core is coated with a coating composition containing (a) a saturated fatty acid or an oil or wax, (b) chitosan and (c) an unsaturated fatty acid or an emulsifier (see Ueda et al. at col. 2, ln. 40-50). The main constituent of the coating is the fatty acid (saturated and unsaturated) and not the chitosan. Chitosan is added as a 'swelling' agent to allow release of the active substance (see Ueda et al. at col. 3, ln. 22-25). Ueda et al. at col. 3, ln. 26-28 state that

> *"... a coating of only chitosan does not provide a sufficient release of active substance."*

Ueda et al. continue at col. 5, ln. 35-48

> *"The amount of chitosan in the coating composition of the present invention normally ranges from 1 to 15 % by weight of the total weight of the coating composition;..... If the contents of chitosan ... and ... are more than the defined ranges ... it becomes difficult to substantially ensure protection of the active substance."*

Thus, Ueda et al. teach away from using chitosan as the only coating material. In fact they teach to stay within the minor proportion of only 1 to 15 %. Yet, chitosan in its interpretation of being a polysaccharide is the only compound mentioned in Ueda et al. which is included in Applicant's list of shell-forming material in Claim 1. Saturated and unsaturated fatty acids are

... The chitosan serves as the "island" in an "island in the sea matrix" to perforate the coating and allow release of the active substance. At no point in time is there a complete surrounding of the core with chitosan, which would be required if chitosan were the coating material according

to Applicant's invention. Therefore, the present invention as a whole is not obvious over Ueda et al.

Claims 8, 9 and 10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ghani (see above). Ghani is cited for its teaching of particular amounts of ingredients.

As explained above Ghani does not anticipate the present invention. Likewise it does not render the present invention obvious. It was an object of Ghani's invention to reduce 'air-borne' dust of enzymes (see Ghani at col. 1, ln. 24). This object has no links to Applicant's problem of providing a stable complex of a biologically active substance and a dietary fiber. There is no motivation for one skilled in the art to apply the teachings of Ghani when looking for a solution to the problem of stable complexes. But even if the skilled person would have considered Ghani, he would not have arrived at Applicant's invention for the reasons explained above (abrasion; perforation of the shell...). Therefore, Ghani fails to render obvious the present invention.

Finally, Claim 11 is rejected under 35 U.S.C. § 103(a) as being obvious over a combination of Ghani and Ardaillon et al. (US 4,877,621). Ardaillon et al. is cited for its disclosure of mixing an active substance into the coating material (shell). The Examiner states that no solvent materials are cited for removal. Yet, Claim 11 as amended calls for a solvent or a dispersion media to be present. Thus, Ardaillon et al. fail to disclose this element of Applicant's claimed process. Moreover, it is not seen how Ardaillon et al. should obviate the present process without the support of primary reference Ghani, which is not applicable to the present invention as argued above.

In view of the foregoing, it is respectfully submitted that the rejections under 35 USC §103(a) should be withdrawn.

Patent Application No. 09/747,850
Docket No. 99/044NUT

Should Examiner Helen F. Pratt have any questions regarding the present application, the Examiner is invited to contact the undersigned.

Respectfully submitted

.....
Klaus Schweitzer
(see attached limited recognition)

ProPat, L.L.C.
2912 Crosby Road
Charlotte, NC 28211
Phone (704) 365-4881
Fax (704) 365-4851

Patent Application No. 09/747,850
Docket No. 99/044NUT

Appendix Indicating Changes to Claims

1.(amended) A multifunctional encapsulated biologically active food component consisting of a core which comprises at least one dietary fiber, which core is surrounded by at least one biologically active substance, in which the core and the biologically active substance(s) are encapsulated by one or more shell-forming substance(s) selected from the group consisting of one or more of the following substances: monosaccharides, disaccharides, polysaccharides, emulsifiers, peptides, proteins and prebiotic substances.

2.(amended) The food component as claimed in claim 1, wherein the dietary fiber is selected from the group consisting of plant fibers ~~(wheat fibers, apple fibers, oat fibers etc.)~~, water-insoluble polysaccharides, ~~(celluloses)~~ ~~and~~ water-soluble polysaccharides, pectins, lignin and plant gums.

5.(amended) The food component as claimed in claim 1, wherein the dietary fiber is selected from the group consisting of one or more of the following substances: plant fibers ~~(wheat fibers, oat fibers, rice dietary fibers, apple fibers, citrus fibers etc.)~~, water-insoluble celluloses, ~~and~~ water-insoluble hemicelluloses, water-soluble polysaccharides ~~(for example β-glucans, fructo- or galactooligosaccharides)~~, pectins, lignins ~~or~~ and plant gums.

6.(amended) The food component as claimed in claim 1, wherein the biologically active substance is selected from the group consisting of one or more of the following substances: probiotic microorganisms, prebiotic substances, enzymes, nutrients ~~(vitamins, minerals, trace elements, amino acids)~~, natural or synthetic secondary

~~(for example flavonoids)~~

11.(amended) A process for producing a food component as claimed in claim 1, which comprises introducing a biologically active substance or a mixture of two or more biologically active substances into a medium which comprises one or more shell-forming substances selected from the group consisting of one or more of the following substances: monosaccharides, disaccharides, polysaccharides, emulsifiers, peptides, proteins and prebiotic substances, then enriching the resultant mixture with one or more dietary fiber(s), wherein one or more substances selected from the group consisting of biologically active substance, the shell-forming substance and the dietary fiber comprises at least one solvent or at least one dispersion media, ~~and~~ then homogeneously mixing the mixture and then freeing it from solvents or dispersion media.

APPENDIX A